



N THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Walter A. Nichols et al.

Application No.: 10/005,155

Filed: December 7, 2001

For: DISPOSABLE INHALER SYSTEM

MAIL STOP ISSUE FEE

Group Art Unit: 3743

Examiner: J. F. Weiss, Jr.

Confirmation No.: 9860

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REQUEST FOR ACKNOWLEDGMENT THAT ALL DOCUMENTS CITED IN MARCH 20, 2002 INFORMATION DISCLOSURE STATEMENT HAVE BEEN CONSIDERED

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants gratefully acknowledge receipt of a Notice of Allowance dated June 30, 2004. However, the Notice of Allowance did not indicate that the documents submitted with the Information Disclosure Statement filed on March 20, 2002 had been considered by the Examiner. For the convenience of the Examiner, a copy of the Information Disclosure Statement and the stamped postcard submitted on March 20, 2002 is enclosed.

The Examiner is requested to initial and return to the undersigned a copy of the subject Form PTO-1449.

In view of the foregoing, the Examiner is requested to make of record the documents submitted with the Information Disclosure Statement filed on March 20, 2002.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: October 14, 2004

Peter K. Ski

Registration No. 31,917

P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620



AVAILABLE COPY

| Inve | entor: Walter A. NICHOLS et al. | | Appln. No. <u>10/005/155</u> | | Filing Date: December 7, 2001 |
|------|---|--------|---|-------|--|
| Doc | ket No.: <u>033018-078</u> | | Work Atty: PKS:ljb | | Date: March 20, 2002 |
| | The following was/were | rece | eived in the U.S. Patent and Trademark (| Offic | e on the date stamped hereon: |
| | Amendment or Response Preliminary Amendment | | Certificate Under 37 C.F.R. § 3.73(b) Transmittal Letter for Missing Parts of Application | | Check for \$ is enclosed Check for \$ is enclosed Charge \$ to Deposit Account |
| | Reply Transmittal Letter Petition for _ Month Extension of Time | | Executed Declaration/Power of Attorney Assignment/Assignment Recordation Form Cover Sheet (PTO-1595) | | Issue Fee Transmittal Payment of Issue Fee and Authorization |
| | Submission of Formal Drawings w/ _ sheet(s) of drawings (Fig(s). 1) | | Claim for Convention Priority w/_ certified copy(s) | | to charge Deposit Account Request for Refund Status Inquiry |
| | Request for Approval of Drawing Changes w/ _ sheet(s) of red ink drawings | ⊠ ⊠ | Information Disclosure Statement w/ document(s) Information Disclosure Citation (PTO-1449) | | Request for Corrected Filing Receipt w/copy of Official Filing Receipt |
| | Notice of Appeal Brief for Appellant | Ø | Information Disclosure Statement Transmittal Letter | | TIPE 3- IDS |
| | Request for Oral Hearing Reply Brief Response to Restriction Requirement | | Request for Corrected Notice of Recordation of Assignment w/copy of Notice Request for Continued Examination | MAD | 200 \$ |
| | or Election of Species Terminal Disclaimer | | | S M | 40EMART OF (10/00) |



Attorney's Docket No. 033018-078

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re P | atent Ap | plication of |) | |
|-----------------------------|-----------|---|-----------------------|--|
| Walter A. NICHOLS et al. | | | | up Art Unit: 3761 |
| Application No.: 10/005,155 | | |)) Exa | miner: Not Yet Assigned |
| Filed: | Decemb | per 7, 2001 |) | |
| For: | SYSTE | SABLE AEROSOL GENERATO OM AND METHODS FOR NISTERING THE AEROSOL | OR) | |
| | | INFORMATION DIS TRANSMI | | |
| | | nissioner for Patents .C. 20231 | | · |
| Sir: | | | | |
| above- | | ed is an Information Disclosure S d patent application. | tatement an | d accompanying form PTO-1449 for th |
| | [X] | No additional fee for submission | of an IDS | is required. |
| | [] | The fee of \$180.00 (126) as set | forth in 37 | C.F.R. § 1.17(p) is also enclosed. |
| | [] | A certification under 37 C.F.R. | § 1.97(e) is | also enclosed. |
| | []. | A certification under 37 C.F.R. in 37 C.F.R. § 1.17(p) are also | | and the fee of \$180.00 (126) as set forth |
| | [] | Charge \$to Depo | sit Account | No. 02-4800 for the fee due. |
| | [] | A check in the amount of \$ | is e | nclosed for the fee due. |
| | 6, 1.17 a | | this paper, | ny appropriate fees under 37 C.F.R. and to credit any overpayment, to duplicate. |
| | | | Respectfully | submitted, |
| | | | Burns, Do | ane, Swecker & Mathis, l.l.p. |
| Alexan (703) 8 | 336-6620 | rginia 22313-1404) | By: Peter Regis | K. Skiff tration No. 31,917 |
| Date: | March 2 | 20, 2002 | | |

Filed 3.20.02 CS

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Patent

Attorney's Docket No. 033018-078

| IN THE UNITED STATES | PATENT | AND | TRADEMARK | OFFICE |
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| Application of | `` | | | |

In re Patent Application of

Walter A. NICHOLS et al.

Application No.: 10/005,155

Filed: December 7, 2001

Ofroup Art Unit: 3761

Examiner: Not Yet Assigned

Ofroup Art Unit: 3761

December 7, 2001

Ofroup Art Unit: 3761

December 3761

For: DISPOSABLE AEROSOL GENERATOR

SYSTEM AND METHODS FOR)
ADMINISTERING THE AEROSOL)

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited on the PTO-Form 1449 is enclosed.

The documents listed on the attached PTO-Form 1449 are cited in commonly owned patents and/or patent applications and/or other wise came to the attention of the Applicants.

The documents are being submitted within 3 months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later, therefore no fee or statement is required under 37 C.F.R. § 1.97(b).

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:

P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620

Date: March 20, 2002

Peter K. Skiff

Registration No. 31,917

DOCKETED (SS filed 3.20.02 (SS

(01/02)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTORNEY'S DKT NO. | APPLICATION NO. | 033018-078 | 10/005,155 |

APPLICANT | Walter A. NICHOLS et al. | GROUP | December 7, 2001 | 3761

| A Property | | e e e | U.S. PATENT DOCUMENTS | |
|----------------------|----------------------|-------------------------|---|-------------------------------------|
| | U.S. Patent Document | | | |
| Examiner Initials | Number | Kind Code (if known) | Name of Patentee or Applicant of Cited Document | Date of Publication (MM-DD-YYYY) |
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

SHEET 2 OF 7

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTORNEY'S DKT NO. APPLICATION NO. 033018-078 10/005,155

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

SHEET 3 OF 7

Substitute for form 1449A/PfQ

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTORNEY'S DKT NO. APPLICATION NO. 033018-078 10/005,155

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and _ not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTORNEY'S DKT NO. APPLICATION NO. 033018-078 10/005,155

APPLICANT
Walter A. NICHOLS et al.
FILING DATE GROUP
December 7, 2001 3761

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and _____ not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

| ATTORNEY'S DKT NO. | APPLICATION NO. |
|--------------------------|-----------------|
| 033018-078 | 10/005,155 |
| APPLICANT | |
| Walter A. NICHOLS et al. | |
| FILING DATE | GROUP |
| December 7, 2001 | 2761 |

Pub. No. Schuster et al. Published 2001/0032647 10-25-2001 A1 FOREIGN PATENT DOCUMENTS Foreign Patent Document Examiner Kind Code **Date of Publication** Translation Initials Number (if known) Country (MM-DD-YYYY) Yes no 667979 A France 10-25-1929 X 354094 A Belgium 09-1928 X 354004 A X Belgium 09-1928 94/09842 A **WIPO** 05-11-1994 98/17131 **WIPO** 04-30-1998 0358114 A 03-14-1990 Europe 0642802 A2 Europe 05-14-1996 1036470 B1 Germany 08-14-1958 X Hungary (Abstract Only) P953409 06-03-1994 207457 A Hungary 04-28-1993 X 168128 B Hungary (Abstract Only) 11-28-1977 Only Hungary (Abstract Only) 03-21-1991 216121 B NON Examiner Initials Barry, P.W. et al. "In Vitro Comparison of the Amount of Salbutamol Available for Inhalation From Different Formulations Used with Different Spacer Devices" Eur Respir J 1997; 10: 1345-1348 Byron, Peter R. Ph.D., Chairman, "Recommendations of the USP Advisory Panel on Aerosols on the USP General Chapters on Aerosols (601) and Uniformity of Dosage Units (905)", Pharmacopeial Forum, Vol. 20, No. 3, pp. 7477-7505, May-June 1994 (023)Hindle, Michael et al., "High Efficiency Aerosol Production Using the Capillary Aerosol Generator" PharmSci 1998; 1: (1: suppl) S211. Hindle, Michael et al., "High Efficiency Fine Particle Generation Using Novel Condensation Technology", Respiratory Drug Delivery VI (eds Dalby, R.N., Byron, P.R. & Farr, S.J.) Interpharm Press, Buffalo Grove, IL 1998 pp 97-102 Hou, Shuguang et al. Solution Stability of Budensonide in Novel Aerosol Formulations Abstract No. 2582, Solid State Physical Pharmacy, November 17, 1998, p. S-307 Kousaka, Yasuo et al., "Generation of Aerosol Particles by Boiling of Suspensions", Aerosol Science and Technology, 21:236-240 (1994) (023)Morén, Folke "Drug Deposition of Pressurized Inhalation Aerosols I. Influence of Actuator Tube Design" AB Draco (Subsidiary of AB Astra, Sweden) Research and Development Laboratories Pack, S-221 01 Lund (Sweden), International Journal of Pharmaceutrics, 1 (1978) 205-212 Newman, Stephen P. et al. "Deposition of Pressurized Suspension Aerosols Inhaled Through Extension

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

Devices¹⁻³" Am Rev Respir Dis 1981; 124:317-320

| | | SHEET _7_ OF _7 |
|---|-----------------------------------|-------------------------------|
| Substitute for form 1449A/PTO | ATTORNEY'S DKT NO. 033018-078 | APPLICATION NO. 10/005,155 |
| INFORMATION DISCLOSURE | APPLICANT Walter A. NICHOLS et al | |
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| Roth, G. et al. High Performance Liquid Chrom Content of the Glucocorticoid Budesonide and Pr | | |

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